5.0 DATA REVIEW

Data review is the process of examining and/or evaluating data to varying levels of detail and specificity by a variety of personnel who have different responsibilities within the data management process. It includes, but is not limited to, data verification, data validation, and data usability assessment. This QAPP element encompasses the data review activities used to ensure that only scientifically sound data that are of known and documented quality and that meet project quality objectives are used in making environmental decisions. The data review approach used for a project must be of a level appropriate to the project requirements.

This chapter defines the steps of data review and describes the elements of its implementation. The chapter's placement in this UFP-QAPP Manual acknowledges that data review takes place after the generation of data. However, the determination of the nature and type of data review that is required to meet Project Quality Objectives begins with the initiation of planning for the project as a whole. Key questions regarding data review, that must be answered during the project planning stage, include but are not limited to:

- What are the Project Quality Objectives (PQOs) deemed necessary to achieve the appropriate level of precision, accuracy, representativeness, comparability, sensitivity, and completeness? (See section 2.7 for discussion of PQOs.)
- What are all the data review inputs, activities, and outputs that will be required for this project? (See Tables 8 and 9 and section 5.2.2 for examples.)
- What entities will be responsible for each step of the data review process and what is the relationship of these entities to those responsible for the data generation process?
- How will the implementation of the data review process and its results integrate with the overall project decision time-line?
- What is the extent of data review and the availability and appropriate use of streamlining tools? (See section 5.4)

Although the data review process outlined below is portrayed as a sequential process, it may be beneficial (and more cost effective) for many projects to combine steps. For example, the entity conducting the data verification, could also conduct the first step of the data validation process.

5.1 Overview

This UFP-QAPP Manual defines three distinct evaluative steps that are used to ensure that project data quality needs are met. As discussed in the QA/QC Compendium (appendix to this

UFP-QAPP Manual describing minimum QA/QC activities), these data review steps are required for all data collected and used in environmental projects. All three steps of data review apply to field sampling activities as well as to the analytical component of data generation.

- **Step I: Sampling and analysis verification** (review for completeness) – confirmation by examination and provision of objective evidence that the specified requirements (sampling and analytical) have been completed.

- **Step II: Sampling and analysis validation** – confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled. Data validation is a sampling and analytical process evaluation that includes evaluating compliance with method, procedure, or contract requirements, and extends to criteria based upon the quality objectives (e.g., PQOs) developed in the QAPP. The purpose of data validation is to assess the performance of the sampling and analysis processes to determine the quality of specified data. It is divided into two subparts:

  -- Step IIa assesses and documents compliance with methods, procedures, and contracts;
  -- Step IIb assesses and documents a comparison with quality objectives of the QAPP.

- **Step III: Data usability assessment** – determination of the adequacy of data, based on the results of data validation and verification, for the decisions being made. The usability step involves assessing whether the process execution and resulting data meet quality objectives based on criteria established in the QAPP.

The table below describes the objectives, scope, steps, and output of data review associated with each process term. The table identifies where the scope of the terms used or the steps involved in the process are expansions of current practice.

Table 8. Data Review Process Summary

Process Term	Objective	Scope	Data Review Step	Output
Data Verification	Review to see if data required for the project is available.	- Sampling* - Analysis	I. Completeness check	Data Verification Report - may be checklist form - package must include all documentation
Data Validation	- Assess and document the performance of the field sample collection process. - Assess and document the performance of the analytical process.	- Sampling* - Analysis	IIa. Compliance with method, procedure, and contract requirements IIb. Compare with project quality criteria from the QAPP*	Data Validation Report - include qualified data - may be part of other report such as RI/FS
Data Usability Assessment*	Assess and document data usability to meet project quality objectives.	- Sampling - Analysis	III. Assess usability of data by considering project quality objectives and the decision to be made*	Usability Report - may be part of other report such as RI/FS

* Denotes when the scope of the terms used or the steps involved are expansions of current practice.

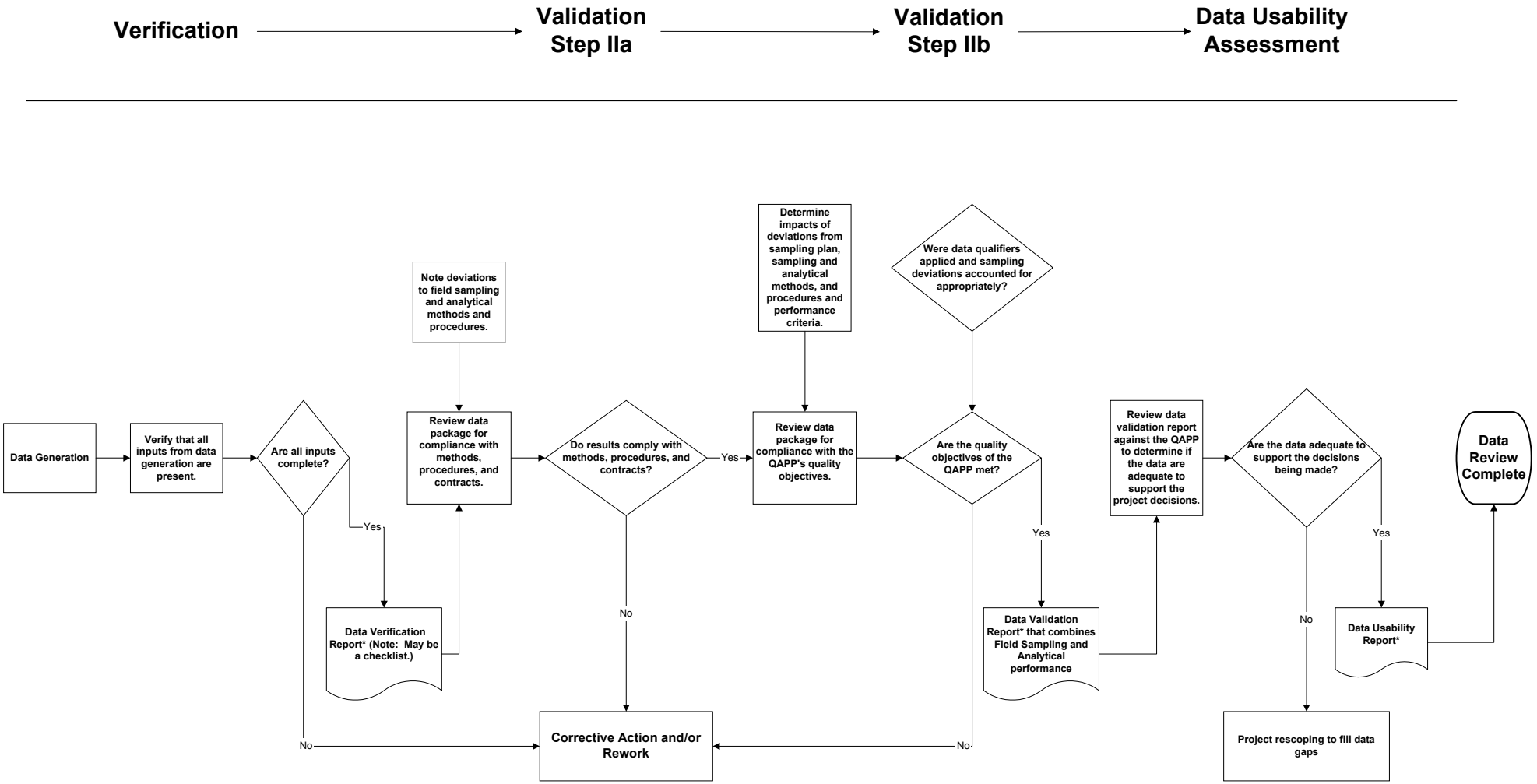
The expansions of scope from current data review practice are based on the following:

- The terms *data verification* and *data validation* apply to field sampling activities as well as to the analytical component of data generation.
- Data validation assesses not only compliance with method, procedure, and contract requirements, but also assesses compliance with QAPP-specific requirements.
- Data usability assessments are a minimum requirement for all environmental project phases and data uses. This is the final step of data review, assessing whether the data are suitable as a basis for the decision.

Figure 36 outlines the data review process described in this UFP-QAPP Manual.

In order to perform the data review steps described above, it is necessary that reported analytical data be supported by complete data packages as defined in the QAPP (see Tables 6 and 7 of Section 3.5.1.3), which include sample receipt and tracking information, chain-of-custody records, tabulated data summary forms and raw analytical data for all field samples, standards, QC checks and QC samples, and all other project-specific documents that are generated.

Figure 36. Data Review Process



* Does not have to be a separate report - may be part of RI/FS or other document.
NOTE: Although the steps shown here are presented in a sequential manner, certain steps in the data review process may be performed simultaneously.

Table 9 lists example inputs for data review and identifies the step of the data review process to which each input applies. These are only example inputs and are not intended to be either a minimum or comprehensive list of inputs.

The reader should note that verification (the completeness step) involves review of all of the data inputs to ensure that they are present. The question answered is "Are the inputs present or not?" (yes or no). This step is not designed to conduct the qualitative review, for example, of compliance that takes place during step IIa of the data validation process. The step is essential, however, to ensure that sufficient information is available for subsequent steps of the data review process.

Request to Reviewers:

These specific requirements for data review were drafted with the CERCLA process in mind. Are they also applicable to other programs? Do the example inputs in Table 9 apply to other programs?

Table 9. Example Inputs to Data Review Process

	Element	Step I Verification	Step IIa Compliance	Step IIb Comparison	Step III Usability
Planning Documents					
1	Evidence of required approval of plan (QAPP)	X			Uses outputs from previous steps
2	Identification of personnel (those involved in the project and those conducting verification steps)	X			
3	Laboratory name	X			
4	Methods (sampling and analysis)	X	X		
5	Performance requirements (including QC criteria) for all inputs	X	X	X	
6	Project quality objectives	X		X	
7	Reporting forms	X	X		
8	Sampling plans/location/maps/grids/sample ID numbers	X	X		
9	Site identification	X			
10	SOPs (sampling and analytical)	X	X		
11	Staff training/certification	X			
12	List of project-specific analytes	X	X		
Analytical (field and fixed lab) Data Package					
13	Case narrative	X	X	X	
14	Internal laboratory chain of custody	X	X		
15	Sample condition upon receipt, and storage records	X	X		

	Element	Step I Verification	Step IIa Compliance	Step IIb Comparison	Step III Usability
Analytical (field and fixed lab) Data Package (cont'd)					
16	Sample chronology (time of receipt, extraction, and analysis)	X	X		Uses outputs from previous steps
17	Identification of QC samples (sampling or lab, temporal, and spatial)	X	X		
18	Associated (batch or periodic) PT results	X	X	X	
19	Communication logs	X	X		
20	Copies of lab notebook, records, prep sheets	X	X		
21	Corrective action reports	X	X		
22	Definitions of lab qualifiers	X	X	X	
23	Documentation of corrective action results	X	X	X	
24	Documentation of individual QC results (e.g., spike, duplicate, LCS)	X	X	X	
25	Documentation of lab method deviations	X	X	X	
26	Electronic data deliverables	X	X		
27	Instrument calibration reports	X	X	X	
28	Laboratory name	X	X		
29	Lab sample identification numbers	X	X		
30	QC sample raw data	X	X	X	
31	QC summary report	X	X	X	
32	Raw data	X	X	X	
33	Reporting forms, completed with actual results	X	X	X	
34	Signatures for lab sign-off (e.g., lab QA manager)	X	X		
35	Standards traceability records (to trace standard source from NIST, for example)	X	X	X	
Sampling Documents					
36	Chain of custody	X	X		
37	Communication logs	X	X		
38	Corrective action reports	X	X	X	
39	Documentation of corrective action results	X	X	X	
40	Documentation of deviation from methods	X	X	X	
41	Documentation of internal QA review	X	X	X	
42	Electronic data deliverables	X	X		
43	Identification of QC samples	X	X	X	
44	Meteorological data from field (e.g., wind, temp)	X	X	X	
45	Sampling instrument decontamination records	X	X		
46	Sampling instrument calibration logs	X	X		
47	Sampling location/plan	X	X	X	
48	Sampling notes/drilling logs	X	X	X	

	Element	Step I Verification	Step IIa Compliance	Step IIb Comparison	Step III Usability
49	Sampling report (from field team leader to PM describing sampling activities)	X	X	X	
External Reports					
50	External audit report	X	X	X	Uses outputs from previous steps
51	External PT results	X	X		
52	Lab certification	X	X		
53	Lab QA Plan	X	X		
54	MDL study information	X	X	X	
55	NELAC accreditation	X	X		

If relevant raw data and/or sample information documenting data quality are not available, then data review cannot be performed. Resampling or reanalysis must be considered.

5.2 Data Review Steps

This sections describes the requirements during QAPP development regarding data review and procedures for implementation of each of the three steps of data review: sampling and analysis verification (step I), sampling and analysis validation (steps IIa and IIb), and data usability assessment (step III). Example activities are provided to clarify the types of procedures that may be performed.

5.2.1 Requirements

The QAPP planning process must establish both the sampling and analysis verification and validation procedures and the sampling and analysis validation criteria. Project-specific validation criteria are developed to identify and qualify data that do not meet the measurement performance criteria as established in Section 2.7. Sampling and analysis verification and validation procedures and criteria are documented in this section of the QAPP to ensure that data are evaluated properly, completely, and consistently for use in meeting project quality objectives. Usability assessment procedures are established and documented in the QAPP to ensure data are appropriately evaluated for usability based on the decision to be made. Validation and usability guidance and documents can be attached to the QAPP.

Specify the process that will be used to verify and validate sample collection, handling, field analysis, and analytical laboratory project data. Identify the specific sampling and analysis validation process that will be used for each analytical parameter, matrix, and concentration level.

Document the procedures and criteria used to verify and validate data information operations. These operations include, but are not limited to, the electronic and/or manual transfer, entry, use, and reporting of data for computer models, algorithms, and databases; correlation studies between variables; data plotting and so forth.

5.2.2 Procedures

This section of the QAPP describes the process that will be followed to verify, validate, and assess usability of project data. Provide a table for both the verification and validation processes that contains the information shown in Figures 37a and b. Examples of the format to be used are provided in Figure 37a. The figures correspond to Optional Worksheets #29a and #29b in the QAPP workbook.

Figure 37a. Sampling and Analysis Verification Step I Process Table

Verification/ Input	Description	Internal/ External	Responsible for Verification (Name, Organization)
Chain of custody	*Chain-of-custody forms will be reviewed internally upon their completion and verified against the packed sample coolers which they represent When everything checks out, the shipper's signature on the COC will be initialed by the reviewer, a copy of the COC will be retained in the site file, and the original and remaining copies will be taped inside the cooler for shipment. See COC SOP for further details.*	*I*	*Cole Lector* *Jewel Engineering*
Analytical data package	*All analytical data packages will be verified internally by the laboratory performing the work for completeness prior to submittal. The laboratory shall complete the appropriate form documenting the organization and complete contents of each data package.*	*I*	*Jasper Sanquin* *Emerald Environmental Lab*
QC summary report	*A summary of all QC sample results will be verified for completeness by the prime contractor upon receipt of data packages from the laboratory.*	*E*	*Joan Finsk* *Whole World Consulting, Inc.*

Figure 37b. Sampling and Analysis Validation Steps IIa and IIb Process Table

Step IIa/IIb	Validation Input	Description	Responsible for Validation (Name, Organization)

Verification or validation inputs include items such as those listed in Table 9 (e.g., chain of custody forms or audit reports). The description should detail how each item will be verified or validated,

when it will occur, and what documentation is necessary. Internal or external is in relation to the data generator (for verification only). The resulting tables will describe the following:

- How sample collection, handling, and field analysis procedures will be verified and validated against the measurement performance criteria specified in Section 2.7.
- How verification and validation of field sampling, handling, and analysis activities will be documented (e.g., QC signatures in field logs, QC checklist, etc.).
- Which sampling, handling, field analytical, and fixed laboratory data will be verified internally at the data generator level.
- The end product of laboratory verification (e.g., laboratory-qualified data).
- Which handling, field analytical, and fixed laboratory data will be verified and validated by entities external to the data generator.
- The matrices, concentration levels, and analytical parameters for which each entity performing sampling and analysis validation will be responsible. It is recommended that this information be provided in a table (see Figure 38).
- The evaluative procedures used in sampling and analysis validation to assess overall measurement error associated with the project and include the data quality indicators (DQIs) described in Section 5.3.

Provide a data validation summary table (for both steps IIa and IIb) that contains the information shown in Figure 38. Identify the matrices, analytical parameters, and concentration levels that each entity performing sampling and analysis validation will be responsible for, as well as the criteria that will be used to validate those data. Examples of the format to be used are provided in Figure 38. Identify by title (lead chemist, project chemist, etc.) and organizational affiliation the person who is ultimately responsible for data validation. This is the person who will sign the project Data Validation Reports. Figure 38 corresponds to Optional Worksheet #29c in the QAPP workbook.

Figure 38. Sampling and Analysis Validation Steps IIa and IIb Summary Table

Step IIa/IIb	Matrix/ Medium	Analytical Parameter or Group	Concentration Level	Validation Criteria	Data Validator (Title and organizational affiliation)
IIa	*Soil*	*VOA*	*Low*	*SW-846 Method 8260B, SOPs*	*Tom Lee, Chemist, Best Review Company*
IIa	*GW*	*Metal*	*Low/Medium*	*SW-846 Method 6010B, SOPs*	*Tom Lee, Chemist, Best Review Company*
IIb	*Soil*	*VOA*	*Low*	*See QAPP section 2.7*	*Paula Simpson, Sr. Chemist, Whatayuk Consulting*

The matrix or medium refers to soil, groundwater, sediment, etc. The analytical parameter or group can be described by common compound groupings such as metals or semi-volatile organic compounds. The concentration level may be a qualitative description (i.e., low, medium, high) as long as the terms are used consistently. For the purposes of this table the validation criteria column may reference an outside guidance document or different section of the QAPP. The title and affiliation of the person who will perform the validation should be included for each entry. This may be different from the person ultimately responsible for the entire data validation.

A data usability assessment considers whether data meet quality objectives as they relate to the decision to be made, and evaluates whether data are suitable for making that decision. All types of data (e.g., field, sampling, fixed lab, analytical) apply to the data usability assessment. The data usability assessment is the final step of data review and can only be performed on data of known and documented quality, that is, verified and validated data.

To accomplish this step of data review, perform the following:

- Summarize the data usability assessment process and all data usability assessment procedures, including statistics, equations, and computer algorithms that will be used to assess data.
- Describe the data generation reporting formats and the documentation that will be generated during data usability assessment.
- Identify the personnel (by title and organizational affiliation) responsible for performing the data usability assessment. Optional Worksheet #30 in the QAPP workbook can be used for this purpose.
- Describe how data will be presented in order to identify trends, relationships (correlations), and anomalies.
- Describe the evaluative procedures used to assess overall measurement error associated with the project and include the DQIs described in Section 5.3.

5.2.2.1 Sampling and Analysis Verification Activities

As described above, verification is simply a completeness check. It is meant to determine whether the required information (the complete data package) is available for further review before the data review process continues. The response is either yes or no. Table 9 (Section 5.1) provides examples of the inputs to which the completeness check is oriented for environmental projects.

5.2.2.2 Validation Step IIa Activities

The activities listed below are examples of specific activities that may occur during an environmental project under step IIa of the sampling and analysis validation process (compliance with methods, procedures, and contracts) for both sampling and analytical data. Although these activities are organized separately, they may be performed at the same time and/or by the same people as the sampling and analysis verification and step IIb of validation. Numbers in parentheses reference the "input numbers" listed in the data review inputs table (Table 9).

Request to Reviewers:

These example activities for data validation were drafted with the CERCLA process in mind. Are they also applicable to other programs?

Data Deliverables and QAPP (Data Package): Ensure that all required information on sampling and analysis from step I was provided (including planning documents, etc.).

Analytes: Ensure that required list(s) of analytes were reported as specified in governing document (i.e., method, procedure, and/or contract).
[uses inputs 4, 7, 12, 24, 33]

Chain-of-Custody: Examine the traceability of the data from time of sample collection until reporting of data. Examine chain-of-custody records against contract, method, and/or procedural requirements.
[uses inputs 14, 20, 29, 30, 32, 36, 43, 47, 48, 49]

Holding Times: Identify holding time criteria and either confirm they were met or document any deviations. Ensure samples were analyzed within holding times specified in method, procedure, or contract requirements. If holding times were not met, confirm that deviations were documented, that appropriate notifications were made, consistent with procedural requirements, and that approval to proceed was received prior to analysis.
[uses inputs 14, 16, 19, 20]

Sample Handling: Ensure that required sample handling, receipt, and storage procedures were followed and any deviations were documented.
[uses inputs 4, 13, 15, 16, 19, 21, 23, 49]

Sampling Methods and Procedures: Establish that required sampling methods were used and any deviations noted. Ensure that the sampling procedures and field measurements met performance criteria and any deviations were documented.
[uses inputs 4, 5, 7, 10, 14, 15, 16, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49]

Field Transcription: Authenticate transcription accuracy of sampling data (i.e., from field notebook to reports).
[uses inputs 36, 42, 43, 44, 45, 49]

Analytical Methods and Procedures: Establish that required analytical methods (fixed lab and field) were used and any deviations noted. Ensure that the QC samples met performance criteria and any deviations were documented.
[uses inputs 4, 5, 7, 10, 13, 15, 16, 17, 20, 22, 24, 25, 26, 27, 28, 30, 31, 32, 33, 34]

Data Qualifiers: Determine that the laboratory data qualifiers were defined and applied as specified in methods, procedures, and contracts.
[uses inputs 22, 30, 31, 32, 33]

Laboratory Transcription: Authenticate transcription accuracy of analytical data (i.e., lab notebook to reporting form or instrument to LIMS).
[uses inputs 26, 28, 29, 30, 31, 32, 33]

Proficiency Testing: Confirm acceptance of PT results against performance requirements as specified in methods, procedures, and/or contracts.
[uses inputs 4, 5, 18, 51]

Standards: Determine that standards are traceable and meet contract, method, and procedural requirements.
[uses input 35]

Communication: Establish that required communication procedures were followed by field or laboratory personnel.
[uses inputs 19, 37]

Audits: Review field and laboratory audit reports and accreditation/certification records for lab's performance on specific methods.
[uses inputs 50, 51, 52, 53, 54, 55]

5.2.2.3 Validation Step IIb Activities

The activities listed below are examples of specific activities that may occur during an environmental project under step IIb of the sampling and analysis validation process (comparison with quality objectives in the QAPP) for both sampling and analytical data. These activities require that the validators have a complete copy of the QAPP and often involve all or parts of the project team. Some of the activities listed in step IIa above have a QAPP-specific review element and are therefore also listed as activities under step IIb below. Numbers in parentheses reference the input numbers listed in the data review inputs table (Table 9).

Request to Reviewers:

These example activities for data validation were drafted with the CERCLA process in mind. Are they also applicable to other programs?

Data Deliverables and QAPP (Data Package): Ensure that the data report from step IIa was provided.

Deviations: Determine the impacts of any deviations from sampling or analytical methods and SOPs. For example, confirm that the methods given in the QAPP were used, and if they were not used, determine if data still meet project MQOs. Consider the effectiveness and appropriateness of any corrective action.
[uses output of step IIa and inputs 13, 21, 23, 25, 27, 38, 39, 40, 41, 50]

Sampling Plan: Determine whether the sampling plan was executed as specified (i.e., the number, location, and type of field samples were collected and analyzed as specified in the QAPP).
[uses inputs 4, 8, 17]

Sampling Procedures: Evaluate whether sampling procedures were followed with respect to equipment and proper sampling support (e.g., techniques, equipment, decontamination, volume, temperature, preservatives, etc.).
[uses inputs 12, 13, 16, 35, 40, 44, 47, 48, 49]

Co-located Field Duplicates: Compare results of co-located field duplicates with criteria established in the QAPP.

[uses inputs 6, 32, 33, 43]

Reporting Limits: Determine that reporting limits were adhered to, as outlined in the QAPP. For exceptionally low detection limits, determine that the laboratory attained the necessary detection limits consistent with the reporting limits for the project.
[uses output of step IIa and inputs 5, 32, 33, 54]

Confirmatory Analyses: Evaluate agreement of laboratory results.

Performance Criteria: Evaluate QC data against project-specific performance criteria in the QAPP (i.e., evaluate quality parameters beyond those outlined in the methods).
[uses inputs 5, 6, 18, 24, 27, 30, 31, 32, 33, 43]

Data Qualifiers: Determine that the data qualifiers applied in step IIa were those specified in the QAPP and that any deviations from specifications were justified.
[uses inputs 22, 30, 31, 32, 33]

5.2.2.4 Data Usability Assessment Activities

The entire project team should reconvene to perform the usability assessment to ensure that the original objectives of the project are understood and the full scope is considered. The activities listed below are examples of specific activities that may occur during an environmental project under the data usability assessment. Numbers in parentheses reference the input numbers listed in the data review inputs table (Table 9).

Request to Reviewers:

These example activities for data usability assessment were drafted with the CERCLA process in mind. Are they also applicable to other programs?

Data Deliverables and QAPP (Data Package): Ensure that all necessary information, including but not limited to data validation, was provided.

Deviations: Determine the impact of deviations on the usability of data.

Sampling Locations, Deviation: Determine if alterations to sample locations continue to satisfy the project objectives.

[uses inputs 6, 47]

Chain-of-Custody, Deviation: Establish that any problems with documentation or custody procedures do not prevent the data from being used for the intended purpose.

Holding Times, Deviation: Determine the acceptability of data where holding times were exceeded.
[uses input 16]

Damaged Samples, Deviation: Determine whether the data from damaged samples are usable. If the data cannot be used, determine whether resampling is necessary.
[uses inputs 4, 6, 15]

PT Results, Deviation: Determine the implications of any unacceptable analytes (as identified by the PT sample results) on the usability of the analytical results. Describe any limitations on the data.
[uses input 18]

QC Samples: Evaluate the implications of unacceptable QC sample results on the data usability for the associated samples. For example, consider the effects of observed blank contamination.
[uses inputs 5, 6, 14, 24, 31, 33, 43, 45]

Matrix: Evaluate matrix effects (interference/bias).
[uses inputs 5, 17, 24, 30, 31, 32, 43, 47]

SOPs and Methods, Deviation: Evaluate the impact of deviations from SOPs and specified methods on data quality.

Meteorological Data and Site Conditions: Evaluate the possible effects of meteorological and site conditions (e.g., wind, rain, temperature) on sample results. Review field reports to identify whether any unusual conditions occurred and how the sampling plan was executed.
[uses inputs 33, 44]

Comparability: Ensure that results from different data collection activities achieve an acceptable level of agreement.

Completeness: Evaluate the impact of missing information. Ensure that enough information was obtained for the data to be usable (completeness as defined in MQOs and PQOs documented in the QAPP).

Background: Determine if background levels have been adequately established (if appropriate).

Critical Samples: Establish that critical samples and critical contaminants of concern (as defined in the QAPP) were collected and analyzed. Determine if the results meet criteria specified in the QAPP.

Data Acceptance Decision/Usability: Determine the usability of the data to make a particular decision considering the implications of all deviations and corrective actions. [uses inputs 23, 25, 33, 40]

5.3 Data Quality Indicators

The following data quality indicators (PARCCS parameters) are important components of the sampling and analysis validation and data usability assessment. A description of how they should be included in the Data Usability Report is found under each parameter heading. Further discussion of the importance of these parameters as they relate to specific QC samples can be found in Section 2.2 of the QA/QC Compendium appendix to this UFP-QAPP Manual.

5.3.1 Precision

Precision is the degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves. Precision is usually expressed as standard deviation, variance, or range, in either absolute or relative terms. Examples of QC measures for precision include field duplicates, laboratory duplicates, matrix spike duplicates, analytical replicates, and surrogates.

In order to meet the needs of the data users, project data must meet the measurement performance criteria for precision specified in Section 2.7.2 of the QAPP. Section 2.2.2 and Table A-1 of the QA/QC Compendium identify QC samples required for projects in the CERCLA process that contribute to the measurement of precision.

Poor overall precision may be the result of one or more of the following: field instrument variation, analytical measurement variation, poor sampling technique, sample transport problems, and/or

spatial variation (heterogeneous sample matrices). In order to identify the cause of imprecision, the field sampling design rationale and sampling techniques should be evaluated by the reviewer, and both field and analytical duplicate/replicate sample results should be reviewed. If poor precision is indicated in both the field and analytical duplicates/replicates, then the laboratory may be the source of error. If poor precision is limited to the field duplicate/replicate results, then the sampling technique, field instrument variation, sample transport, and/or spatial variability may be the source of error.

If Data Validation Reports indicate that analytical imprecision exists for a particular data set or sample delivery group (SDG), then the impact of that imprecision on data usability must be discussed in the Data Usability Report.

The Data Usability Report should discuss and compare overall field duplicate precision data from multiple data sets collected for the project for each matrix, analytical parameter, and concentration level. Data Usability Reports should describe the limitations on the use of project data when overall precision is poor or when poor precision is limited to a specific sampling or laboratory/analytical group, data set/SDG, matrix, analytical parameter, or concentration level.

When project-required precision is not achieved and project data are not usable to adequately address environmental questions (i.e., determining if regulatory/technical action limits have been exceeded) and to support project decision-making, then the Data Usability Report should address how this problem will be resolved and discuss the potential need for resampling.

5.3.2 Accuracy/Bias

Accuracy is the degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components, which are due to sampling and analytical operations. Examples of QC measures for accuracy include PT samples, matrix spikes, laboratory control samples (LCSs), and equipment blanks.

In order to meet the needs of the data users, project data must meet the measurement performance criteria for accuracy/bias specified in Section 2.7.2 of the QAPP. Section 2.2.2 and Tables A-2 and A-3 of the QA/QC Compendium identify QC samples required for projects in the CERCLA process that contribute to the measurement of accuracy.

The Data Usability Report should discuss and compare overall contamination and accuracy/bias data from multiple data sets collected for the project for each matrix, analytical parameter, and

concentration level. The Data Usability Report should describe the limitations on the use of project data if extensive contamination and/or inaccuracy/bias exists or when inaccuracy is limited to a specific sampling or laboratory/analytical group, data set/SDG, matrix, analytical parameter, or concentration level. The Data Usability Report should identify qualitative and/or quantitative bias trends in multiple PT sample results for each matrix, analytical parameter, and concentration level. The impact of any qualitative and/or quantitative trends in bias on the sample data should be discussed. **Any PT samples that have false positive and/or false negative results should be reported and the impact on data usability should be discussed in the Data Usability Report.**

When project-required accuracy/bias is not achieved and project data are not usable to adequately address environmental questions (i.e., determining if regulatory/technical action limits have been exceeded) and to support project decision-making, then the Data Usability Report should address how this problem will be resolved and discuss the potential need for resampling.

5.3.3 Representativeness

Representativeness is the measure of the degree to which data accurately and precisely represent a characteristic of a population, a parameter variation at a sampling point, a process condition, or an environmental condition.

In order to meet the needs of the data users, project data must meet the measurement performance criteria for sample representativeness specified in Section 2.7.2 of the QAPP.

Discuss how the QA/QC activities (review of sampling SOPs, field sampling TSAs, split sampling and analysis audits, etc.) and QC check and sample data will be reviewed to assess sample representativeness. If field duplicate precision checks indicate potential spatial variability, then this may trigger additional scoping meetings and subsequent resampling in order to collect data that are more representative of a nonhomogeneous site.

The Data Usability Report should discuss and compare overall sample representativeness for each matrix, parameter, and concentration level. Data Usability Reports should describe the limitations on the use of project data when overall nonrepresentative sampling has occurred or when nonrepresentative sampling is limited to a specific sampling group, data set/SDG, matrix, analytical parameter, or concentration level. If data are not usable to adequately address environmental questions and/or support project decision-making, then the Data Usability Report should address how this problem will be resolved and discuss the potential need for resampling.

5.3.4 Comparability

Comparability is the degree to which different methods, data sets, and/or decisions agree or can be represented as similar. Comparability describes the confidence (expressed qualitatively or quantitatively) that two data sets can contribute to a common analysis and interpolation.

In order to meet the needs of the data users, project data must meet the measurement performance criteria for comparability specified in Section 2.7.2 of the QAPP.

Include methods/formulas for assessing data comparability for each matrix, analytical parameter, and concentration level.

Different situations require different assessments of comparability.

- If two or more sampling procedures and/or sampling teams will be used to collect samples, describe how comparability will be assessed for each matrix, analytical parameter, and concentration level.
- If two or more analytical methods/SOPs will be used to analyze samples of the same matrix and concentration level for the same analytical parameter, describe how comparability will be assessed between the two data sets.
- If field screening data will be confirmed by full-protocol methods, document the specific method references and percent difference formula that will be used to assess comparability for individual data points (refer to Section 2.7.2). To document overall comparability, describe the procedures used to perform overall assessment of comparability and include mathematical and/or statistical formulas for evaluating screening and confirmatory data comparability.
- If split samples are analyzed for EPA oversight, document the specific method references and percent difference formula that will be used to assess split sample comparability for individual data points (refer to Section 2.7.2). To document overall comparability, describe the procedures used to perform overall assessment of oversight split sampling comparability and include mathematical and/or statistical formulas for evaluating oversight split sampling data comparability. Section 2.2.2 of the QA/QC Compendium recommends that split samples be used only when accompanied by a batch-specific PT sample for proper evaluation of results.
- If it is a long-term monitoring projects, project data should be compared to previously generated data to ascertain the possibility of false positives and/or false negatives, and positive and/or negative trends in bias. Data comparability is extremely important in these situations. Anomalies detected in the data may reflect

a changing environment or indicate sampling and/or analytical error. Comparability criteria should be established to evaluate these data sets in order to identify outliers and trigger resampling as warranted.

The Data Usability Report should discuss and compare overall comparability between multiple data sets collected for the project for each matrix, analytical parameter, and concentration level. The Data Usability Report should describe the limitations on the use of project data when project-required data comparability is not achieved for the overall project or when comparability is limited to a specific sampling or laboratory/analytical group, data set/SDG, matrix, analytical parameter, or concentration level.

If screening/confirmatory comparability criteria are not met, then this should be documented in the Data Usability Report and the impact on data usability should be discussed. Likewise, if oversight split sampling comparability criteria are not met, then the Data Usability Report should document this and discuss the impact on data usability. If data are not usable to adequately address environmental questions and/or support project decision-making, then the Data Usability Report should address how this problem will be resolved and discuss the potential need for resampling.

Finally, if long-term monitoring data are not comparable, then the Data Usability Report should address whether the data indicate a changing environment or are a result of sampling and/or analytical error. If data are not usable to adequately address environmental questions and/or support project decision-making, then the Data Usability Report should address how this problem will be resolved and discuss the potential need for resampling.

5.3.5 Sensitivity and Quantitation Limits

Sensitivity is the capability of a test method or instrument to discriminate between measurement responses representing different levels (e.g., concentrations) of a variable of interest. Examples of QC measures for determining the sensitivity include laboratory-fortified blanks, a method detection limit study, and calibration standards at the quantitation limit.

In order to meet the needs of the data users, project data must meet the measurement performance criteria for sensitivity and QLs specified in Section 2.7.2 of the QAPP. Section 2.2.2 and Table A-4 of the QA/QC Compendium identifies QC samples required for projects in the CERCLA process that contribute to the measurement of sensitivity.

Include methods/formulas for calculating analytical sensitivity that ensure QLs are achieved (e.g., percent recovery of laboratory-fortified blank compounds). Also, include procedures for evaluating

low point calibration standards run at the QL. Low point calibration standards should produce a signal at least 10 times the background noise level and should be part of a linear calibration curve.

Document the procedures for calculating MDLs, QLs, and SQLs.

If Data Validation Reports indicate that sensitivity and/or QLs were not achieved, then the impact of that lack of sensitivity and/or higher QLs on data usability must be discussed in the Data Usability Report.

The Data Usability Report should discuss and compare overall sensitivity and QLs from multiple data sets collected for the project for each matrix, analytical parameter, and concentration level. Data Usability Reports should describe the limitations on the use of project data if project-required sensitivity and QLs were not achieved for all project data or when sensitivity is limited to a specific sampling or laboratory/analytical group, data set/SDG, matrix, analytical parameter, or concentration level.

When project-required QLs are not achieved and project data are not usable to adequately address environmental questions (i.e., determining if regulatory/technical action limits have been exceeded) and to support project decision-making, then the Data Usability Report should address how this problem will be resolved and discuss the potential need for resampling. In this case, the Data Usability Report should clearly differentiate between usable and unusable data for the data users.

5.3.6 Completeness

Completeness is a measure of the amount of valid data obtained from a measurement system compared with the amount that was expected to be obtained under correct, normal circumstances.

In order to meet the needs of the data users, project data must meet the measurement performance criteria for data completeness specified in Section 2.7.2 of the QAPP.

Include the methods/formulas for calculating data completeness. Describe how the amount of valid data will be determined as a percentage of the number of valid measurements that should have been collected for each matrix, analytical parameter, and concentration level. When certain sample locations and/or analytes and matrices are more critical than others in making project decisions, describe how critical data will be assessed for completeness.

The Data Usability Report should discuss and compare overall completeness of multiple data sets collected for the project for each matrix, analytical parameter, and concentration level. Data

Usability Reports should describe the limitations on the use of project data if project-required completeness was not achieved for the overall project or when completeness is limited to a specific sampling or laboratory/analytical group, data set/SDG, matrix, analytical parameter, or concentration level.

When project-required completeness is not achieved and sufficient data are not available to adequately address environmental questions and support project decision-making, then the Data Usability Report should address how this problem will be resolved and discuss the potential need for additional resampling.

5.3.7 Data Limitations and Actions from Data Usability Assessment

Describe what actions will be taken when data do not meet the project quality objectives. It is necessary to document, in this section of the QAPP, the exact process for handling data that do not meet project quality objectives (i.e., when DQIs do not meet measurement performance criteria). Depending on how those data will be used, the process should specify the restrictions on use of those data for environmental decision-making.

Sources of sampling and analytical error should be identified and corrected as close as possible to the onset of sample collection activities. Incorporating an ongoing data assessment process throughout the project, rather than just as a final step, will facilitate the early detection and correction of problems, thereby ensuring that project quality objectives are met.

5.4 Streamlining Data Review Steps

Streamlining data review refers to a process of eliminating some requirements for data validation (steps IIa and IIb) that are deemed no longer necessary to preserve data integrity. Streamlining data review is meant to reduce time and costs, while still confirming the quality of the data. Thus, any streamlining option should recognize that:

- The type and amount of data reviewed should be sufficient to develop a clear understanding of the quality of the data.
- The practice of reviewing a subset of data (or of a data indicator such as a successful PT sample) as a substitute for review of all data should be reevaluated if problems are detected that call into question the quality of the data set.

Streamlining data review occurs when efficiencies are created in the data review process by the following actions:

- Looking at a subset of data that is representative of a larger universe.
- Examining the data in an alternative manner (e.g., through the use of batch-specific PT samples).

Different EPA Regions, DoD components, and DOE facilities have negotiated a variety of streamlining options with different projects. The decision as to the nature and type of streamlining to be conducted will be determined on a site-by-site or facility-by-facility basis and documented in the QAPP. The QAPP should also contain decision criteria that allow for revision of the initial streamlining plan. For example, decision criteria contained in the QAPP could specify that if problems are identified in the investigation, then streamlining cannot occur. Other factors may also lead to a revision of the initial streamlining decision, such as intense political interest and concern on the part of the community. A clause should be present in the QAPP that prohibits streamlining when conditions are not optimal.

Applicability of streamlining options is addressed in three ways: the data review **step** to which streamlining may be applicable, the **criteria** for considering the streamlining of data review, and the **level and type** of streamlining to be applied. Each of these is addressed below.

5.4.1 Data Review Steps To Be Streamlined

Streamlining of data review steps is negotiated on a project-specific basis, in accordance with the criteria outlined below, and is documented in the project-specific QAPP. The critical decision to streamline data review or not occurs as part of **step IIa** of the data validation process (compliance with method, procedural, and contractual requirements) and subsequent steps that rely on outputs from step IIa.

The role of streamlining in the three data review steps is outlined below.

Sampling and Analysis Verification - Step I, verification, requires a completeness check of all of the field and analytical data associated with the project. It is not subject to streamlining. This verification should first be conducted by the environmental laboratory (for analytical data) and by the prime contractor (for both field sampling and analytical data). It may be conducted externally.

Sampling and Analysis Validation - Validation step IIa (compliance with method, procedural, and contractual requirements) may be streamlined based on criteria described below (Section 5.4.2). The amount of streamlining and the type of information to be

streamlined will be negotiated on a project-by-project basis that takes into account the cost implications of streamlining analytical data validation and review of field sampling data outputs, while maintaining sufficient representativeness to ensure quality. Validation step IIb (consistency with QAPP-specific requirements) will be streamlined to the degree that step IIa has been streamlined, as step IIb relies on the outputs of step IIa.

Data Usability Assessment - Step III, the data usability assessment, will be streamlined to the degree that step IIa is streamlined, given that data usability relies upon outputs from previous steps.

5.4.2 Criteria for Streamlining Data Review

The following criteria are evaluated qualitatively on a project-specific basis to determine the extent to which a streamlined data review process for validation steps IIa and IIb is appropriate:

- Level of risk associated with the contaminants of concern at the site (not always known in the planning stage).
- Cost and schedule demands of the overall project (could drive a decision to implement streamlining that may speedup the project and reduce costs).
- The specific decisions for which the data will be used (e.g., risk assessment or determination of whether further investigation is required).
- Complexity of analysis (may suggest that more streamlining, in the case of simple analyses, or less streamlining, in the case of highly complex analyses, is appropriate).
- Ability to identify critical (most significant) samples and focus data review on those samples.
- Political attention to project (could drive more streamlining, in the case of time pressures, or less streamlining, in the case of potential elevated risks).
- Results of project-specific audits that suggest that problems exist or that the contractors are performing high-quality work.
- Sampling events that include recurring samples (i.e., monthly or quarterly long-term monitoring of the same chemicals could lead to streamlined data validation for these events).
- Proximity of results to action levels (and therefore the risks associated with a low level of confidence). For example, analytical levels that are close to action levels may require a higher level of confidence (and a greater amount of data validation) than levels that are considerably above action levels and for which data validation is not likely to show a difference in the presence or absence of risk.
- Availability of successfully performed batch-specific PT samples. The PT sample

should be of a similar matrix, contaminant make-up, and concentration as the environmental samples being tested, and quantitative acceptance criteria should be established. Batch-specific PT samples may be used to streamline the analytical portion of data validation only. Section 2.2.3 of the QA/QC Compendium summarizes the issues surrounding a requirement for batch-specific PT samples and Section 2.3.3.2 describes the circumstances that may allow their use as a tool to streamline data validation.

5.4.3 Amounts and Types of Data Appropriate for Streamlining

The amounts and types of data to be streamlined (for steps IIa and IIb), as well as the nature of the streamlining activity, will be determined by site-specific circumstances. A number of options are possible; some examples are presented below:

- Only a specific percentage (e.g., 10 percent) of all data sets will be validated, unless a problem is identified.
- Only a specific percentage of all data sets will be validated, but all critical samples, as identified in the QAPP, will undergo full data review.
- Only a specified percentage of all data sets will be validated, but that validation will include recalculation of raw data.
- All data are validated, but only a percentage of raw data is reviewed and recalculated.
- Successful batch-specific PT samples may substitute for validation of all or some of the analytical data.

It should be noted that the term "data validation" has traditionally applied to analytical data. As noted here, the term applies to both field sampling activities and analytical data. Since the environmental community has more experience with data validation for analytical data, it is easier to identify some logical options for that process. The examples described above are therefore oriented toward analytical data.